K060915

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

{as required by 21 CFR, section 807.92(c)}

FOR

KIRWAN SERIES of ANEURYSM CLIPS and APPLIERS

MODELS: 45.XXX, SERIES of KIRWAN L-ANEURYSM-CLIPS and APPLIERS, and 65.XXX, SERIES of KIRWAN YASARGIL-TYPE ANEURYSM CLIPS and APPLIERS.

Common name: Aneurysm Clip / Aneurysm Clip Applier.

Classification name: Aneurysm Clip / Aneurysm Clip Applier (§882.5200 & 882.4175, respectively)

Product code: HCH & HCI, respectively.

Devices Class: Class II

The Kirwan 45.XXX and 65.XXX Series of Aneurysm Clips are intended for either temporary or permanent occlusion of intracranial aneurysms. They are also intended to be applied exclusively with the 45.XXX and 65.XXX Series Appliers.

Technological safety and effectiveness is established by the fact that these clips do not contain any new technological risks or characteristics when compared to the legally marketed devices offered here as predicates. They are manufactured according to prevailing standards with the technological characteristics of each clip listed on its labeling.

Kirwan Surgical Products, Inc.
180 Enterprise Drive
Marshfield, MA 02050
Phone: (781) 834-9500
Fax: (781) 834-0022
Contact: Kevin P. Prario, Regulatory Affairs Manager
Date prepared: 3/24/2006

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There are no applicable performance standards listed for these devices under Section 514 of the Food, drug and Cosmetic Act. Nonetheless, Kirwan 45.XXX and 65.XXX series devices have been tested and manufactured in accordance with prevailing standards and guidelines in order to assure safety and efficacy. Kirwan aneurysm clips and appliers have been found to comply with the requirements of the applicable sections within the following standards and guidelines;

- ISO 9713, Neurosurgical implants – Self-closing intracranial aneurysm clips.
- ISO 5832-2, Metallic Materials – Part 2: Unalloyed titanium.
- ISO 5832-3, Metallic Materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy for surgical implant applications.
- ISO 5832-7, Metallic Materials – Part 2: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy.
- F 67 – 95, Standard Specification for unalloyed Titanium for Surgical Implant Applications.
- F 1058 – 97, Standard Specification for; Wrought Cobalt-Chromium-Nickel-Molybdenum-Iron Alloys for Surgical Implant Applications.
- F 136 – 98, Standard Specification for; Wrought Titanium - 6Aluminum – 4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications.

Safety and hazard analysis has determined that the hazard conditions for the 45.XXX and 65.XXX Aneurysm Clips and Appliers range in the low-to-moderate level and for this reason are acceptable.

Therefore, the 45.XXX and 65.XXX Aneurysm Clips and Appliers are substantially equivalent in intended use, technological safety and effectiveness and performance to the following predicates;

- 65.XXX /T Series, REBSTOCK Implant Steel Aneurysm Clips & Titanium Aneurysm Clips.
- 55XXX Series, PERNECZKY ANEURYSM CLIP.
- FT XXX T Series / FE XXX K Series, AESCULAP YASARGIL ANEURYSM CLIP, (TITANIUM or PHYNOX).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kirwan Surgical Products, Inc.
% Mr. Kevin Prario
Regulatory Affairs Manager
180 Enterprise Drive
Marshfield, Massachusetts 05050

APR 17 2007

Re: K060915
Trade/Device Name: Models: 45.XXX, Series of Kirwan L-Aneurysm-Clips and Appliers, and 65.XXX, Series of Kirwan Yasargil-Type Aneurysm Clips and Appliers
Regulation Number: 21 CFR 882.5200
Regulation Name: Aneurysm clip
Regulatory Class: II
Product Code: HCH
Dated: January 16, 2007
Received: January 17, 2007

Dear Mr. Prario:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060915

Indications for Use

510(k) Number (if known): _____

Device Name:

Models: 45.XXX, Series of Kirwan L-Aneurysm-Clips and Appliers, and 65.XXX, Series of Kirwan Yasargil-Type Aneurysm Clips and Appliers.

Indications for Use:

The Kirwan 45.XXX and 65.XXX Series of Aneurysm Clips are intended for either temporary or permanent occlusion of intracranial aneurysms. They are also intended to be applied exclusively with the Kirwan 45.XXX and 65.XXX Series Appliers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060915